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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,194	09/17/2001	Mark E. Gurney	29915/6177PCP	3788

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EXAMINER
NICHOLS, CHRISTOPHER J

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 03/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/806,194	GURNEY ET AL.	
	Examiner	Art Unit	
	Christopher Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *151-300* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *151-300* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

2. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

3. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 241-250, 254-269, 279-280 (each in part), drawn to a method for producing a polypeptide comprising *SEQ ID NO: 2* comprising polynucleotide encoding *SEQ ID NO: 2*, vectors, and host cells comprising same, and the polypeptide comprising *SEQ ID NO: 2*.

Group 2, claim(s), 151-157, 162-188, 241-249, 251, 254-269, and 279-280 (each in part), drawn to a method for producing a polypeptide comprising *SEQ ID NO: 4* comprising polynucleotide encoding *SEQ ID NO: 4*, vectors, and host cells comprising same, and the polypeptide comprising *SEQ ID NO: 4*.

Group 3, claim(s) 151-152, 158-160, 162-171, 173-188, 241-249, 254-269, and 279-280 (each in part), drawn to a method for producing a polypeptide comprising *SEQ ID NO: 6* comprising polynucleotide encoding *SEQ ID NO: 6*, vectors, and host cells comprising same, and the polypeptide comprising *SEQ ID NO: 6*.

Group 4, claim(s) 151-152, 161-165, 167-169, 173-188, 252, 254-269, and 279-280 (each in part), drawn to a method for producing a polypeptide comprising *SEQ ID NO: 8* comprising the polynucleotide encoding *SEQ ID NO: 8*, vectors, and host cells comprising same, and the polypeptide comprising *SEQ ID NO: 8*.

Group 5, claim(s) 189-195 and 197-200 (each in part), drawn to a method of identifying agents that **inhibit** the activity of human Asp2 aspartyl protease (Hu-Asp2) comprising *SEQ ID NO: 4*.

Group 6, claim(s) 189-194 and 196-200 (each in part), drawn to a method of identifying agents that **inhibit** the activity of human Asp2 aspartyl protease (Hu-Asp2) comprising *SEQ ID NO: 6*.

Group 7, claim(s) 201 (in part), drawn to a method for identifying agents that **modulate** the activity of Asp2 aspartyl protease wherein the hybrization partner comprises *SEQ ID NO: 4*.

Group 8, claim(s) 201 (in part), drawn to a method for identifying agents that **modulate** the activity of Asp2 aspartyl protease wherein the hybrization partner comprises *SEQ ID NO: 6*.

Group 9, claim(s) 281-292, drawn to a method for identifying agents that **modulate** the activity of Asp2 aspartyl protease using *SEQ ID NO: 1* and *SEQ ID NO: 2*.

Group 10, claim(s) 202, 203, 219, 220, 224, 225, 293, 294, drawn to a method for treating Alzheimer's disease and medicaments thereof.

Group 11, claim(s) 204-218, drawn to a method for assaying **modulators** of β-secretase activity.

Group 12, claim(s) 221-223 (each in part), drawn to a method for identifying agents that **inhibit** the activity of human Asp2 aspartyl protease (Hu-Asp2) using *SEQ ID NO: 4*.

Group 13, claim(s) 221-223 (each in part), drawn to a method for identifying agents that **inhibit** the activity of human Asp2 aspartyl protease (Hu-Asp2) using *SEQ ID NO: 6*.

Group 14, claim(s) 226-231 and 295-299 drawn to a method of reducing cellular production of amyloid beta (Aβ) from amyloid precursor protein using an **anti-sense reagent**.

Group 15, claim(s) 232-240, 270-272, 274-278 (each in part), drawn to a polypeptide comprising the amino acid sequence of a mammalian amyloid protein precursor (APP) or fragment thereof, polynucleotides, and host cells comprising same wherein the isoform comprises *SEQ ID NO: 16*.

Group 16, claim(s) 232-240, 270-271, 273-278 (each in part), drawn to a polypeptide comprising the amino acid sequence of a mammalian amyloid protein precursor (APP) or fragment thereof, polynucleotides, and host cells comprising same wherein the isoform comprises *SEQ ID NO: 18*.

Group 17, claim(s) 232-240, 270-271, 273-278 (each in part), drawn to a polypeptide comprising the amino acid sequence of a mammalian amyloid protein precursor (APP) or fragment thereof, polynucleotides, and host cells comprising same wherein the isoform comprises *SEQ ID NO: 20*.

Group 18, claim(s) 253, drawn to an isolated antibody.

Group 19, claim(s) 300 (in part), drawn to a method for the identification of an agent that decreases the activity of a Hu-Asp1 polypeptide.

Group 20, claim(s) 300 (in part), drawn to a method for the identification of an agent that decreases the activity of a Hu-Asp1(a) polypeptide.

Group 21, claim(s) 300 (in part), drawn to a method for the identification of an agent that decreases the activity of a Hu-Asp2(b) polypeptide.

4. The inventions listed as Groups 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, and 21 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

5. Group 1 recites a method for producing a polypeptide comprising SEQ ID NO: 2 comprising polynucleotide encoding *SEQ ID NO: 2*, vectors, and host cells comprising same, and the polypeptide comprising *SEQ ID NO: 2*, which is not required by any of the other groups.

6. Group 2 recites a method for producing a polypeptide comprising *SEQ ID NO: 4* comprising polynucleotide encoding *SEQ ID NO: 4*, vectors, and host cells comprising same, and the polypeptide comprising *SEQ ID NO: 4*, which is not required by any of the other groups.

7. Group 3 recites a method for producing a polypeptide comprising *SEQ ID NO: 6* comprising polynucleotide encoding *SEQ ID NO: 6*, vectors, and host cells comprising same, and the polypeptide comprising *SEQ ID NO: 6*, which is not required by any of the other groups.

8. Group 4 recites a method for producing a polypeptide comprising *SEQ ID NO: 8* comprising the polynucleotide encoding *SEQ ID NO: 8*, vectors, and host cells comprising same, and the polypeptide comprising *SEQ ID NO: 8*, which is not required by any of the other groups.

9. Group 5 recites a method of identifying agents that inhibit the activity of human Asp2 aspartyl protease (Hu-Asp2) comprising *SEQ ID NO: 4*, which is not required by any of the other groups.

10. Group 6 recites a method of identifying agents that inhibit the activity of human Asp2 aspartyl protease (Hu-Asp2) comprising *SEQ ID NO: 6*, which is not required by any of the other groups.

11. Group 7 recites a method for identifying agents that **modulate** the activity of Asp2 aspartyl protease wherein the hybrization partner comprises *SEQ ID NO: 4*, which is not required by any of the other groups.

12. Group 8 recites a method for identifying agents that **modulate** the activity of Asp2 aspartyl protease wherein the hybrization partner comprises *SEQ ID NO: 6*, which is not required by any of the other groups.

13. Group 9 recites a method for identifying agents that modulate the activity of Asp2 aspartyl protease using *SEQ ID NO: 1* and *SEQ ID NO: 2*, which is not required by any of the other groups.

14. Group 10 recites a method for treating Alzheimer's disease and medicaments thereof, which is not required by any of the other groups.

15. Group 11 recites a method for assaying **modulators** of β-secretase activity, which is not required by any of the other groups.

16. Group 12 recites a method for identifying agents that **inhibit** the activity of human Asp2 aspartyl protease (Hu-Asp2) using *SEQ ID NO: 4*, which is not required by any of the other groups.

17. Group 13 recites a method for identifying agents that **inhibit** the activity of human Asp2 aspartyl protease (Hu-Asp2) using *SEQ ID NO: 6*, which is not required by any of the other groups.

18. Group 14 recites a method of reducing cellular production of amyloid beta (Aβ) from amyloid precursor protein using an **anti-sense reagent**, which is not required by any of the other groups.

19. Group 15 recites a polypeptide comprising the amino acid sequence of a mammalian amyloid protein precursor (APP) or fragment thereof, polynucleotides, and host cells comprising same wherein the isoform comprises *SEQ ID NO: 16*, which is not required by any of the other groups.

20. Group 16 recites a polypeptide comprising the amino acid sequence of a mammalian amyloid protein precursor (APP) or fragment thereof, polynucleotides, and host cells comprising same wherein the isoform comprises *SEQ ID NO: 18*, which is not required by any of the other groups.

21. Group 17 recites a polypeptide comprising the amino acid sequence of a mammalian amyloid protein precursor (APP) or fragment thereof, polynucleotides, and host cells comprising same wherein the isoform comprises *SEQ ID NO: 20*, which is not required by any of the other groups.

22. Group 18 recites an isolated antibody, which is not required by any of the other groups.

23. Group 19 recites a method for the identification of an agent that decreases the activity of a Hu-Asp1 polypeptide, which is not required by any of the other groups.

24. Group 20 recites a method for the identification of an agent that decreases the activity of a Hu-Asp1(a) polypeptide, which is not required by any of the other groups.

25. Group 21 recites a method for the identification of an agent that decreases the activity of a Hu-Asp2(b) polypeptide, which is not required by any of the other groups.

26. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

27. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher James Nichols, Ph.D. whose telephone number is (703) 305-3955. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D. can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
February 27th, 2003

Gary A. Kunz
GARY KUNZ
SUPERVISORY PATENT EXAMINER
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